K103782 P1/3

TOMTEC
IMAGING SYSTEMS

December 10th, 2010

JAN 2 7 2011

Special 510(k) Summary

4D MV-Assessment 2.0

Owner's Name and Address
TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

Contact Person
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QM & RA Officer
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Common, Classification & Proprietary Names

Common Name:	Various Ultrasound Image Analysis Software
Classification Name:	Programmable diagnostic computer
Proprietary Name(s):	**4D MV-Assessment 2.0**

Predicate Devices:

Predicate Device 1	K071232	Image-Arena Platform 3.0; Research-Arena Platform 2.0; Echo-Com 3.0; Image-Com 3.0; 4D Cardio-View 2.0; 4D LV-Analysis 2.5; 4D RV-Function 1.0; 4D MV Assessment 1.2; 4D LV-Function 2.0 **Only 4D MV-Assessment 1.2 component and 4D LV-Analysis 2.5 component,** TomTec Imaging Systems GmbH
Predicate Device 2	K090461	Image-Arena 4.0 and Image-Arena Applications with 2D Cardiac Performance Analysis 1.0 TomTec Imaging Systems GmbH

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Device Description

4D MV-Assessment© is a clinical application package for high performance PC platforms based on Microsoft® Windows® operating system standards.
4D MV-Assessment is software for the retrieval, reconstruction, rendering and analysis of digitized ultrasound B-mode images and Color Doppler images. The data is acquired by ultrasound machines that are able to store compatible 3D/4D datasets. The digital 3D/4D data can be used for comprehensive morphological and functional assessment of the mitral valve.
4D MV-Assessment is compatible with different TomTec Image-ArenaTM platforms, their derivatives or any other platform that provides and supports the Generic CAP Interface. Platforms enhance the workflow by providing the database, import, export and other functionalities. All analyzed data and images will be transferred to the platform for reporting and statistical quantification purposes.
4D MV-Assessment is designed for 2-, 3- and 4-dimensional morphological and functional analysis of mitral valves (MV). Based on an easy and intuitive workflow the application package generates models of anatomical structures such as MV annulus, leaflet and the closure line. Automatically derived parameters allow quantification of pre- and post-operative valvular function and comparison of morphology.
4D MV-Assessment improves the presentation of anatomy and findings to surgeons and cardiologists and visualizes the complex morphology and dynamics of the mitral valve.
The Generic CAP Interface is used to connect clinical application packages (=CAPs) to platforms to exchange digital medical data.

Intended Use

4D MV Assessment is intended to retrieve, analyze and store digital ultrasound images for computerized 3-dimensional and 4-dimensional (dynamic 3D) image processing.
4D MV Assessment reads certain digital 3D/4D image file formats for reprocessing to a proprietary 3D/4D image file format for subsequent 3D/4D tomographic reconstruction and rendering. It is intended as a general purpose digital 3D/4D ultrasound image processing tool for cardiology.

Indications for use

4D MV-Assessment 2.0 is intended as software to analyze pathologies related to the mitral valve.

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Technological Characteristics Comparison

For detailed comparison of all software functionalities of the subject device and the predicate devices refer to Chapt.12: Substantial Equivalent discussion.

Discussion according non-clinical performance data testing

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing, was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Discussion according clinical performance data testing

The overall product concept was clinically accepted and the clinical test results support the conclusion that the subject device is as safe as effective, and performs as well as the predicate devices. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Test Conclusions of non-clinical and clinical performance data

Test results support the conclusion, that the subject device is as safe as effective, and performs as well as or better than the predicate devices. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Munich, December 10th, 2010

Inge Scheidt
QM & RA Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TomTec Imaging Systems GmbH
c/o Ms. Inge Scheidt
QM & RA Officer
Edisonstrasse 6
85716 Unterschleissheim
Unterschleissheim, Germany D-85716

JAN 27 2011

Re: K103782
Trade/Device Name: 4D MV-Assessment 2.0
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: December 10, 2010
Received: December 27, 2010

Dear Ms. Scheidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

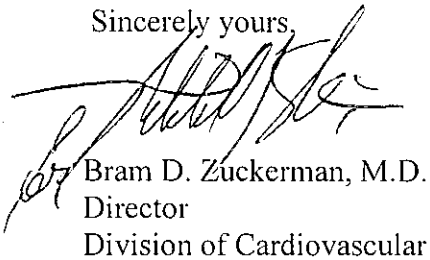
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103782

Device Name:

4D MV-Assessment 2.0

Indications for Use:

MV-Assessment 2.0 is intended as software to analyze pathologies related to the mitral valve.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 11/27/2011

Division of Cardiovascular Devices

510(k) Number K103782